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**REMARKS****Introductory Comments:**

Claims 1-27 were examined in the Office Action under reply and stand variously rejected under (1) 35 U.S.C. §102 (claims 1-5, 6, 8, 10, 12 and 14-25); and (2) 35 U.S.C. §103(a) (claims 1, 3 and 5-26). These rejections are respectfully traversed as discussed more fully below.

Applicants acknowledge with appreciation the withdrawal of the previous rejections under 35 U.S.C. §112, first paragraph.

**Overview of the Above Amendments:**

Claims 1, 4 and 5 have been amended to recite the subject invention with greater particularity. These claims now recite that the polynucleotide is “isolated.” Additionally, claims 1 and 4 recite the E1E2 antigen “comprises an HCV E1 polypeptide and an HCV E2 polypeptide.” Applicants submit these amendments are appropriate as they place the application in condition for allowance and do not present subject matter that would require an additional search as the term “E1E2” antigen as used in the previous claims clearly encompassed antigens comprising both E1 and E2 polypeptides.

Support for these amendments can be found throughout the specification at, e.g., pages 12-13, bridging paragraph; page 3, lines 1-5; and page 18, lines 1-3. The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing the unamended claims.

**Rejections Over the Art:**

Claims 1-5, 10, 14, 15 and 17-25 remain rejected under 35 U.S.C. §102(b) as anticipated by Ishi et al., *Hepatology* (1998) 28:1117-1120 (“Ishi”). The Office argues:

The composition comprising a polynucleotide encoding an HCV E1E2 antigen of claim 1 reads on HCV particles. The subjects had administered to them the virus as shown by the antibody responses. While it is unfortunate that accidents happen, the subjects did have a composition comprising a polynucleotide encoding HCV E1E2 administered to them. The specification

does not define ‘administer’ but in the paragraph spanning pages 14-15 discusses nucleic acid immunization. There is nothing in that section that specifically limits the term ‘administer.’

Office Action, page 3. However, applicants respectfully disagree.

As previously explained, Ishi studied antibody responses to HCV structural proteins in patients already infected with HCV virus. HCV virus was not “administered” to patients, as required by the claims. Applicants disagree with the Office’s interpretation of the term “administering.” This term is clearly understood in the art to mean purposeful delivery, as opposed to passive or accidental infection through contact with individuals or with blood of individuals infected with HCV.

It is seminal that “[i]n construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to ‘particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.’” *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 59 USPQ2d 1401, 1407 (Fed. Cir. 2001) (citing 35 U.S.C. §112, second paragraph). Thus, claim terms are to be given their ordinary and customary meaning unless it is apparent from the patent and the prosecution history that the inventor used the term in a manner having a different meaning. *Hoechst Celanese Corp. v. BP Chems. Ltd.*, 38 USPQ2d 1126, 1129 (Fed. Cir. 1996).

The ordinary and customary meaning of a claim term may be determined by reviewing a variety of sources. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, No. 02-1145 (Fed. Cir. June 27, 2003). Some of these sources include the claims themselves, see, *Process Control Corp. v. HydReclaim Corp.*, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999), as well as dictionaries, encyclopedias and treatises. *Texas Digital Systems Inc. v. Telegenix Inc.*, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002). In fact, very recent case law upholds the concept that dictionaries are to be considered before consulting the specification and prosecution history in order to arrive at the ordinary meaning of a claim term. *Intellectual Property Development, Inc. v. UA-Columbia Cablevision or Westchester, Inc.*, No. 02-1248 (Fed. Cir. July 21, 2003).

Thus, in order to evidence that the term “administering” is well known to include an active, purposeful delivery, applicants are appending excerpts from two dictionaries -- Webster’s Ninth New Collegiate Dictionary and The Concise Oxford Dictionary of Current English.

Meanings for the term “administer” found in Webster’s Dictionary include to dispense and to give remedially, as to give a dose of medicine. Definitions for the term “administer” in the Oxford Dictionary include to provide, apply. Thus, for this reason alone, the present claims distinguish over Ishi.

Nevertheless, solely in an effort to advance prosecution, applicants have amended claims 1, 4 and 5 to recite that the composition includes an “isolated” polynucleotide. Applicants’ specification explains that an isolated polynucleotide is a “nucleic acid molecule devoid, in whole or part, of sequences normally associated with it in nature; or a sequence, as it exists in nature, but having heterologous sequences in association therewith.” Thus, the fact that subjects were accidentally infected with HCV virus particles as described in Ishi does not anticipate the present method claims. Accordingly, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Claims 1, 3, 5, 6, 8, 10, 12 and 14-17 were rejected under 35 U.S.C. §102(a) over Forns et al., *Vaccine* (1999) 17:1992-2002 (“Forns”). The Office argues “Forns discloses a polynucleotide that encodes a E2 protein with and without P7 that can be used for eliciting an immune response to HCV E2.” Office Action, page 4. The Office further asserts that the nucleic acid of Forns, i.e., the polynucleotide encoding a fragment of E2, reads on a polynucleotide encoding an E1E2 antigen based on the definition of antigen in applicants’ specification. Applicants respectfully disagree.

In particular, a review of the specification demonstrates that applicants clearly intended the term “E1E2 antigen” to mean an antigen with both E1 and E2 polypeptides, and not a fragment of E1E2 that completely lacks E1 and includes only a fragment of E2, as interpreted by the Office. For example, at page 18, lines 1-3 the specification explains that an E2 polypeptide can be combined with an E1 polypeptide to form an E1E2 polypeptide.

Nevertheless, in an effort to advance prosecution, the claims now recite that the E1E2 antigen “comprises an HCV E1 polypeptide and an HCV E2 polypeptide.” Forns clearly does not administer a polynucleotide encoding an E1E2 antigen comprising an HCV E1 polypeptide and an HCV E2 polypeptide, as claimed. Thus, Forns also does not anticipate the claims and this basis for rejection should be withdrawn.

Claims 1, 3 and 5-26 were rejected under 35 U.S.C. §103(a) as unpatentable over Forns. The Office asserts for the reasons discussed above that Forns teaches a method of eliciting an immune response against the antigens recited by applicants. However, as previously explained, Forns immunized mice with one of three different plasmids as follows: (1) a plasmid containing the entire sequence of the E2 and p7 genes (pE2); (2) a plasmid encoding a truncated form of the E2 protein targeted to the cell surface (pE2surf); and (3) a control plasmid lacking an HCV insert (pDisplay). Forns did not deliver a polynucleotide encoding the full-length E2 gene without the p7 gene, as claimed herein. Nor did Forns administer a polynucleotide encoding an E1E2 antigen comprising an E1 polypeptide and an E2 polypeptide, also as claimed. Moreover, Forns does not teach or suggest administering a polynucleotide that is produced intracellularly and not secreted when expressed in cells of the subject, as claimed. To reiterate, Forns specifically targeted the HCV E2 protein to the cell surface.

Thus, there is no teaching or suggestion to use antigens as claimed by applicants in methods to elicit an immune response. Applicants submit, therefore, that the rejection under 35 U.S.C. §103 should also be withdrawn.

**CONCLUSION**

Applicants respectfully submit that the claims define a patentable invention.

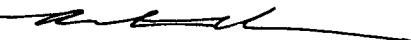
Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further written communications in this application to:

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Respectfully submitted,

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# The Concise Oxford Dictionary of Current English

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## adiabatic

**ide<sup>2</sup>** /ɪdə/ *suffix forming nouns (decade) (cf. -AD<sup>1</sup>)* [French *-ade* from Greek *-as-ada*]

**ide<sup>3</sup>** /ɪdə/ *suffix forming nouns: 1 = -ADE<sup>1</sup> (brocade). 2 a person concerned (renegade). [Spanish or Portuguese *-ado*, masc. form of *-ada*; see -ADE<sup>1</sup>]*

**denine** /'dɪmɪn/ *n. a purine derivative found in all living tissue as a component base of DNA or RNA. [German *Adenin* from Greek *adēn* 'gland'; see -INE<sup>4</sup>]*

**denoids** /'dɪmɔɪdz/ *n. pl. Med. a mass of enlarged lymphatic tissue between the back of the nose and the throat, often hindering speaking and breathing in the young. □ adenoidal /'nɔɪd(ə)l/ adj. [Greek *adēn* 'gland' + -OID]*

**denoma** /'dɪnəʊmə/ *n. (pl. adenomas or adenomata /-mətə/) a glandlike benign tumour. [modern Latin from Greek *adēn* 'gland' + -OMA]*

**denosine** /'dēnōsīn/ *n. a nucleoside of adenine and ribose present in all living tissue in combined form. [ADENINE + RIBOSE]*

**denosine triphosphate** *n. a nucleotide important in living cells, whose breakdown to the diphosphate provides energy for physiological processes (abbr: ATP).*

**dept adj. & n. □ adj. /'dɛpt, ə'dɛpt/ (foll. by *at, in*) thoroughly proficient. □ n. /'dɛpt/ a skilled performer, an expert. □ adeptly adv. adeptness n. [Latin *adēptus* past part. of *adipisci* 'attain']**

**dequate** /'dɪkweɪt/ *adj. 1 sufficient, satisfactory (often with the implication of being barely so). 2 (foll. by *to*) proportionate. 3 barely sufficient. □ adequacy n. adequately adv. [Latin *adēquatus*, past part. of *adēquare* 'make equal' (as AD, *aēquus* 'equal')]*

**deux** /du: 'də: French a *de* / *adv.* & *adj.* 1 for two. 2 between two. [French]

**ed fin.** /ad'fɪm/ *abbr. at or near the end. [Latin ad finem]*

**adhere** /'dɪhər/ *v. intr. 1 (usu. foll. by *to*) (of a substance) stick fast to a surface, another substance, etc. 2 (foll. by *to*) behave according to; follow in detail (*adhered to our plan*). 3 (foll. by *to*) give support or allegiance to. [French *adhérer* or Latin *adhaerēre* (as AD, *haerē* 'stick')]*

**adherent** /'dɪhərənt/ *n. & adj. □ n. 1 a supporter of a party, person, etc. 2 a devotee of an activity. □ adj. (foll. by *to*) faithfully observing a rule etc. 2 (often foll. by *to*) (of a substance) sticking fast. □ adherence n. [French *adhérent* (as ADHERE)]*

**Usage** See Usage Note at ADHESION.

**adhesion** /'adhɪ:ʒ(ə)n/ *n. 1 the act or process of adhering. 2 the capacity of a substance to stick fast. Med. an abnormal union of surfaces due to inflammation or injury. 4 the maintenance of contact between the wheels of a vehicle and the road. 5 the giving of support or allegiance. [French *adhésion* (as Latin *adhaesio* (as ADHERE))]*

**Usage** Adhesion is more common in physical sense (e.g. *The glue has good adhesion*), with adherence used in abstract senses (e.g. *adherence to principles*).

**adhesive** /'adhɪsɪv, -zɪv/ *adj. & n. □ adj. stick enabling surfaces or substances to adhere to each other. □ n. an adhesive substance, esp. one used to stick other substances together. □ adhesively adv. adhesiveness n. [French *adhésif-ive* (as ADHERE)]*

**adhibit** /'adhɪbɪt/ *v. tr. (adhibited, adhibiting) 1 affix, apply or administer (a remedy). □ administer /'adhr'bi:t(ə)n/ n. [Latin *adhibere* *adhibit-* (as AD, *habet* 'have')]*

**ad hoc** /ad 'hɒk/ *adv. & adj. for a particular (usually exclusive) purpose (an *ad hoc* appointment). [Latin *ad hoc* 'this']*

**ad hominem** /ad 'hōmɪnɛm/ *adv. & adj. 1 relating to or associated with a particular person. 2 (of an argument) appealing to the emotions and not to reason. [Latin *ad hominem* 'to the person']*

**adiabatic** /'eɪdɪə'bætɪk, 'aɪdɪə-/ *adj. & n. Physics □ adj. impassable to heat. 2 occurring without heat entering*

## adieu

or leaving the system. □ n. a curve or formula for adiabatic phenomena. □ adiabatically *adv.* [Greek *adiabatos* 'impassable' (as A-, *diabaino* 'pass')] □ adieu /'eɪdju:/ *int. & n. □ int. goodbye. □ n. (pl. adieus or adieux /'eɪdju:z/ a goodbye. [Middle English from Old French, from *à* 'to' + *Dieu* 'God']*

**ad infinitum** /ad in'fɪnɪtəm/ *adv. without limit; for ever. [Latin, = to infinity]*

**ad interim** /ad 'ɪntərɪm/ *adv. & adj. for the meantime. [Latin, = between times]*

**adios** /'aɪdʒəs/ *int. goodbye. [Spanish *adiós*, from *a* 'to' + *Diós* 'God']*

**adipocere** /'aɪdɪpə(u)'sɪə/ *n. a greyish fatty or soapy substance generated in dead bodies subjected to moisture. [French *adipocire*, from Latin *adeps adipis* 'fat' + French *cire* 'wax' from Latin *cera*]*

**adipose** /'aɪdɪpəs, -z/ *adj. of or characterized by fat, esp. as stored in the body tissues, fatty. □ adiposity /'aɪdɪp'ozɪtɪ/ n. [modern Latin *adipositas* from *adeps adipis* 'fat']*

**adit** /'aɪdɪt/ *n. 1 a horizontal entrance or passage in a mine. 2 a means of approach. [Latin *aditus* (as AD, *itus* from *ire* 'go')]*

**Adiavasi** /'aɪdɪvəsɪ/ *n. (pl. Adiavasis) a member of the aboriginal tribal peoples of India. [Hindi *ādīvāsī* 'original inhabitant']*

**Adj.** /'aɪdʒ/ *abbr. (preceding a name) Adjutant.*

**adjacent** /'aɪdʒəs(ə)nt/ *adj. (often foll. by *to*) lying near or adjoining. □ adjacency n. [Middle English from Latin *adīcēre* 'to be near' (as AD, *acēre* 'lie')]*

**adjective** /'aɪdʒɪktɪv/ *n. & adj. □ n. a word or phrase naming an attribute, added to or grammatically related to a noun to modify it or describe it. □ adj. additional; not standing by itself, dependent. □ adjectival /'aɪdʒɪktɪv(ə)l/ adj. adjectivally /'aɪdʒɪktɪv'əlɪ/ adv. [Middle English from Old French *adjectif* 'ive, ultimate', from Latin *adīcere* 'to add, throw to, add, attribute' in the phrase *nomen adjectivus* 'attributive noun' (as AD, *acēre* 'throw')]*

**adjoin** /'aɪdʒɔ:n/ *v. tr. 1 be next to and joined with. 2 *archaic* [Am. 1] [Middle English via Old French *ajonner* from Latin *adīungere* *adjunct-* (as AD, *īungere* 'join')]*

**adjourn** /'aɪdʒn/ *v. tr. 1 put off; postpone. b break off (a meeting, discussion, etc.) with the intention of resuming it. 2 intr. of persons at a meeting: a break off proceedings and disperse. b (foll. by *to*) transfer the meeting to another place. [Middle English from Old French *ajourner* (as AD, *jorn* 'day', ultimately from Latin *diurnal* (cf. JOURNAL, JOURNEY)]*

**adjourned** /'aɪdʒnɪd/ *adj. [Cf. JOURNAL] adjourning or being adjourned.*

**adjournment** /'aɪdʒnment/ *n. Brit. a debate in the House of Commons on the motion that the House be adjourned, esp. an opportunity for raising various matters.*

**adjudge** /'aɪdʒdʒ/ *v. tr. 1 adjudicate (a matter). 2 (often foll. by *to* + clause, or *to* + infin.) pronounce judgment on. 3 (foll. by *to*) award judicially. 4 *archaic* judgement /'aɪdʒdʒm(ə)nt/ n. adjudicative /'aɪdʒdɪk'tɪv/ adj. (also adjudication)*

*[Middle English Old French *ajuger* from Latin *adīdicare* (as AD, *dicere* 'say'). See ADJUDICATE]*

**adjur** /'aɪdʒər/ *v. tr. 1 *thr.* act as judge in a court, tribunal, etc. 2 tr. a decide finally regarding a claim etc. b (foll. by *to*) be pronounced (as adjudged to be bankrupt). □ adjur /'aɪdʒər/ n. adjudicative /'aɪdʒdɪk'tɪv/ adj. [Latin *adīdicare* (as AD, *dicere* 'say')]*

**adjunct** /'aɪdʒənt/ *n. (foll. by *to* or *of*) a subordinate or thing. 2 an assistant; a subordinate person, with temporary appointment only. 3 Gram. a phrase used to amplify or modify the meaning of words or words in a sentence. □ adjunctive /'aɪdʒəktɪv/ adj. [Latin *adīgūtus* (see ANTHONY)]*

**adjure** /'aɪdʒər/ *v. (usu. foll. by *to* + infin.) charge or command, esp. earnestly, esp. under*

## 17.

## administration

oath. □ adjuration /'aɪdʒʊ'reɪʃ(ə)n/ n. adjuratory /-rət(e)rɪ/ adj. [Middle English from Latin *adjurare* (as AD, *jurare* 'swear') in Late Latin sense 'put a person to an oath']

**adjust** /'aɪdʒəst/ v. 1 tr. a arrange; put in the correct order or position. b regulate, esp. by a small amount. 2 tr. (usu. foll. by *to*) make suitable. 3 tr. harmonize (discrepancies). 4 tr. assess (loss or damages). 5 intr. (usu. foll. by *to*) make oneself suited to; become familiar with (adjust to one's surroundings). □ adjustable /'aɪdʒəstəbəl/ adj. adjuster /'aɪdʒəstər/ n. [French *ajuster* from Old French *ajuster* 'near']

**adjutant** /'aɪdʒʊt(ə)nt/ n. 1 a Mil. an officer who assists superior officers by communicating orders, conducting correspondence, etc. b an assistant. 2 (in full: adjutant bird) a large black and white S. Asian stork of the genus *Leptoptilos*. □ adjutancy n. [Latin *adjutare*, frequentative of *adjuware*; see ADJUVANT]

**Adjutant General** n. (pl. Adjutant Generals) a high-ranking army administrative officer.

**adjuvant** /'aɪdʒʊvənt/ adj. & n. □ adj. 1 helpful, auxiliary. 2 Med. (of therapy) applied after initial treatment for cancer, esp. to suppress secondary tumour formation. □ n. 1 an adjuvant; person or thing. 2 Med. a substance which enhances the body's immune response to an antigen. [French *adjuvant* or Latin *adjuware* (as AD, *juvare* 'help')]

**Adlerian** /'aɪdlerɪən/ adj. of or relating to A. Adler, Austrian psychologist d. 1937, or his system of psychology.

**ad lib** /ad'lib/ v. *adj., adv., & n. □ v. intr. (ad libbed, ad libbing) speak or perform without formal preparation; improvise. □ adj. improvised. □ adv. as one pleases; to any desired extent. □ n. something spoken or played extempore. [abbreviation of AD LIBITUM]*

**ad libitum** /ad'libɪtəm/ *adv. = AD LIB. adv. [Latin, = according to pleasure]*

**ad litem** /ad'li:təm/ *adj. (of a guardian-etc.) appointed for a lawsuit. [Latin]*

**Adm.** abbr. (preceding a name) Admiral.

**adman** /'aɪdmən/ n. (pl. admen) *colloq. a person who produces advertisements commercially.*

**admass** /'aɪdmas/ n. esp. Brit. the section of the community that is regarded as readily influenced by advertising and mass communication.

**admeasure** /'aɪmɛʒə/ v. tr. archaic apportion; assign in due shares. □ admeasurement n. [Middle English via Old French *amēsurer* from medieval Latin *admensurare* (as AD, MEASURE)]

**admin** /'aɪmɪn/ n. Brit. colloq. administration. [abbreviation]

**adminicle** /'aɪdɪmɪk(ə)l/ n. 1 a thing that helps. 2 (in Scottish law) collateral evidence of the contents of a missing document. □ adminicular /'aɪdɪmɪk(j)ʊlər/ adj. [Latin *adminiculum* 'prop']

**administer** /'aɪdɪmɪstər/ v. 1 tr. attend to the running of (business affairs etc.); manage. 2 tr. a be responsible for the implementation of (the law, justice, punishment, etc.). b Eccl. give out, or perform the rites of (a sacrament). c (usu. foll. by *to*) direct the taking of (an oath). 3 tr. a provide, apply (a remedy). b give, deliver (a rebuke). 4 intr. act as an administrator. □ administrable adj. [Middle English via Old French *administre* from Latin *administrare* (as AD, MINISTER)]

**administrate** /'aɪdɪmɪstret/ v. tr. & intr. administer (esp. business affairs); act as an administrator. [Latin *administrare* (as ADMINISTER)]

**administration** /'aɪdɪmɪ'streɪʃ(ə)n/ n. 1 a management of a business, institution, etc. b (prec. by the) N. Amer. the people responsible for this, regarded collectively. 2 the management of public affairs; government. 3 the government in power; the ministry. 4 N. Amer. the term of, office, of a political leader or government. 5 (Administration) (in the US) a government agency (the Food and Drug Administration). 6 Law the management

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